EXHIBIT 2

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:21-cv-09011-RGK-GJS	Date	September 26, 2022
Title	***Ravgen, Inc. v. Quest Diagnostics Incorporated***		

Present: The Honorable	R. GARY KLAUSNER, UNITED STATES DISTRICT JUDGE	
Krystal Hernandez	Not Reported	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiff:	Attorneys Present for Defendant:	
Not Present	Not Present	

Proceedings: **(IN CHAMBERS) Order Re: Quest's Motion for Summary Judgment [DE 260, 330] and Ravgen's Motion for Partial Summary Judgment [DE 264, 326]**

I. INTRODUCTION

On May 2, 2022, Ravgen, Inc. ("Ravgen") filed a First Amended Complaint ("FAC") against defendants Quest Diagnostics, Incorporated and Quest Diagnostics Nichols Institute (collectively "Quest"). (ECF No. 168.) In the FAC, Ravgen asserts that Quest has infringed on two patents: (1) Patent No. 7,727,720 ("'720 Patent") and (2) Patent No. 7,332,277 ("'277 Patent") (collectively "Patents-in-Suit"). On May 16, 2022, Quest filed an Answer and Counterclaims ("Counter Compl.") against Ravgen asserting, among other things, non-infringement of the Patents-in-Suits and that the Patents-in-Suit are unenforceable due to inequitable conduct. (ECF Nos. 176, 181.)

Presently before the Court are Quest's Motion for Summary Judgment (Quest Mot., ECF Nos. 260, 330) and Ravgen's Motion for Partial Summary Judgment (Ravgen Mot., ECF Nos. 264, 325, 326.)

For the following reasons, the Court **GRANTS IN PART and DENIES IN PART** Quest's Motion and **DENIES** Ravgen's Motion.

II. FACTUAL BACKGROUND

The following facts are undisputed, unless otherwise noted:

A. Ravgen and the '277 Patent

Ravgen is a "diagnostics company that focuses on non-invasive prenatal testing." (FAC ¶ 2.) Ravgen's founder, Dr. Ravinder Dhallan, has patented the two Patents-in-Suit. (*Id.*) Dr. Dhallan applied for the '277 Patent on September 11, 2003. (Ravgen's Statement of Genuine Dispute of Material Fact

("Ravgen's GDMF") No. B1, ECF Nos. 249, 324.) Dr. Dhallan along with attorney Dr. Michael Cronin, prosecuted the application the '277 Patent. (*Id.* at No. B2.) The '277 Patent is directed at a non-invasive method to detect chromosomal abnormalities in a fetus. (Dowd Decl., Ex. 1 ("'277 Patent", ECF No. 260.) Claim 125[1] of the '277 Patent depends from Claim 1 of the '277 Patent. ('277 Patent at Claims 1, 4, 8, 9, 10, 125.) Claim 1 of the '277 Patent states in full:

> A method for detecting the presence or absence of a fetal chromosomal abnormality, said method comprising: quantitating a ratio of the relative amount of alleles at a heterozygous locus of interest in a mixture of template DNA, wherein said mixture comprises maternal DNA and fetal DNA, and wherein said mixture of maternal DNA and fetal DNA has been obtained from a sample from a pregnant female, and further wherein said heterozygous locus of interest has been identified by determining the sequence of alleles at the locus of interest, and wherein said ratio indicates the presence or absence of a fetal chromosomal abnormality.

(*Id.* at Claim 1.)

B. Quest and the Accused Product QNatal

Quest Diagnostics Incorporated and its subsidiaries market a non-invasive prenatal screening test for certain fetal abnormalities under the trade name "QNatal Advanced" ("QNatal"). (Counter Compl. ¶ 6.) Quest Nichols operates a laboratory, is a wholly owned subsidiary of Quest Diagnostics Incorporated, and offers QNatal testing in California. (Counter Compl. ¶ 17.) QNatal is the accused product.

QNatal uses "whole genome sequencing which looks at DNA fragments across the full length of the human genome in a given sample." (Ravgen's GDMF at Nos. at A13.) QNatal "uses a DNA sequencing machine to read millions of DNA fragments for a given sample, using a technique called 'massively parallel shotgun sequencing[.]'" (Ravgen's GDMF at Nos. at A14.) The parties dispute the intricate details of QNatal.

Quest asserts that "the outputs of QNatal's sequencing steps are called 'sequence reads'—the nucleotide sequences of DNA fragments from random positions across all chromosomes over the full length of the 3-billion nucleotide-long genome." (Quest's Statement of Uncontroverted Facts and Conclusions of Law, ("Quest's SUF") No. A15, ECF Nos. 260, 330.) Thereafter, according to Quest,

[1] Ravgen has narrowed the asserted claims of the '277 Patent to claims 125 and 132. (Ravgen Mot. at 1, fn. 1.)

once the DNA is sequenced for a sample, an algorithm "aligns" each sequence read from the patient's sample against a "reference" genome to place each into one of thousands of equal sized "bins." (*Id.* at No. A17.) Quest asserts that the QNatal algorithm counts the total number of sequence reads that have successfully aligned and been placed in a bin and determines a z-score for each bin. (*Id.* at Nos. A20-21.) According to Quest, the "z-score" is calculated by:

> (1) taking the total count of aligned sequence reads for a given bin in the patient's sample and subtracting the "expected" count for that bin based on a data set compiled from approximately 5,000 other nonpatient samples obtained from normal pregnancies (the "reference data set") and (2) dividing that value by the median deviation from the "expected" count in the reference data set (i.e., how much each of the samples in the reference data set varied from the "expected" count and taking the median (midpoint) of the variances).

(*Id.* at No. A21.) The parties do not dispute that each bin is a 50,000-nucleotide-long section of the 3-billion nucleotide-long reference genome. (Ravgen's GDMF No. A18.) But Quest asserts that its sequence reads are not limited to specific alleles or their alternative forms at a particular position. (Quest's SUF No. A16.) Ravgen counters that Quest's QNatal test "determines the sequence of nucleotides, which are representative of alleles for a particular position on a chromosome, present for the DNA fragment sequences." (Ravgen's GDMF No. A16.)

III. JUDICIAL STANDARD

Under Federal Rule of Civil Procedure 56(a), a court may grant summary judgment only where "there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). On issues where the moving party does not have the burden of proof at trial, the moving party is required only to show that there is an absence of evidence to support the non-moving party's case. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986). Upon such a showing, the Court may grant summary judgment on all or part of the claim. Fed. R. Civ. P. 56(a).

Where the moving party bears the burden of proof at trial, it can prevail on summary judgment only where it presents evidence that "establish[es] beyond controversy every essential element" of the movant's claim or affirmative defense. *S. Cal. Gas Co. v. City of Santa Ana*, 336 F.3d 885, 888 (9th Cir. 2003) (internal quotation marks omitted). Upon such showing, the court may similarly grant summary judgment "on all or part of the claim." Fed. R. Civ. P. 56(a)–(b).

To defeat a summary judgment motion, the non-moving party may not merely rely on its pleadings or on conclusory statements. *See Celotex*, 477 U.S. at 324. Nor may the non-moving party

merely attack or discredit the moving party's evidence. *Nat'l Union Fire Ins. Co. v. Argonaut Ins. Co.*, 701 F.2d 95, 97 (9th Cir. 1983). Rather, the non-moving party must affirmatively present specific evidence sufficient to create a genuine issue of material fact for trial. *See Celotex Corp.*, 477 U.S. at 324.

IV. DISCUSSION

Quest's moves for summary judgment on three discrete issues. First, Quest argues that QNatal does not infringe on the '277 Patent Claim 125 either literally or under the doctrine of equivalents. Second, Quest argues that the '277 Patent is unenforceable due to inequitable conduct toward the United States Patent and Trademark Office ("PTO"). Third, Quest argues that under a Patent Licensing Agreement ("PLA"), between Ravgen and a third-party, Quest is released from liability for infringing conduct arising before June 23, 2021.

Ravgen's Motion seeks partial summary judgment on the latter two issues: that Quest is not released under the PLA and that the '277 Patent is not unenforceable for inequitable conduct.

Because a finding in Quest's favor as to whether Quest is released under the PLA would limit Quest's liability, the Court address that issue first. The Court then addresses the issues of infringement and inequitable conduct.

For the reasons set forth below, the Court **GRANTS IN PART** and **DENIES IN PART** Quest's Motion and **DENIES** Ravgen's Motion.

A. Quest is Released from Liability for Pre-June 23, 2021 Conduct

Quest argues that under the PLA executed between Ravgen and a third-party licensee (hereinafter "Licensee"), Quest is released from any alleged past infringement occurring before June 23, 2021. Ravgen also moves for summary judgment on this issue arguing Quest is not released under the PLA. The Court agrees with Quest.

Neither party disputes that Delaware law governs the interpretation of the PLA. (*See* e.g., Quest's Response to Ravgen's Statement of Undisputed Facts ("Quest's RSUF") No. 22, ECF No. 329.) "Delaware adheres to an objective theory of contracts, meaning that a contract's construction should be that which would be understood by an objective, reasonable third party." *Cox Commc'ns, Inc. v. T-Mobile US, Inc.*, 273 A.3d 752, 760 (Del. 2022). Under Delaware law, "great weight" is placed "on the plain terms of a disputed contractual provision, and [Courts] interpret clear and unambiguous terms according to their ordinary meaning." *Id.* Extrinsic evidence is not considered unless the text is ambiguous, and "[a]mbiguity is present only when the provisions in controversy are reasonably or fairly

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susceptible of different interpretations or may have two or more different meanings." *Id.* A "contractual provision is not rendered ambiguous simply because the parties in litigation differ as to the proper interpretation." *Id.* "If parties introduce conflicting interpretations of a term, but one interpretation better comports with the remaining contents of the document or gives effect to all the words in dispute, the court may, as a matter of law and without resorting to extrinsic evidence, resolve the meaning of the disputed term in favor of the superior interpretation." *Wills v. Morris, James, Hitchens & Williams*, No. CIV. A. 15297, 1998 WL 842325, at *2 (Del. Ch. Nov. 6, 1998) (citing to *E.I. du Pont de Numours and Co., Inc. v. Shell Oil Co.*, 498 A.2d 1108, 1113 (Del. 1985).

The PLA between Ravgen and Licensee includes the following release:

> **Ravgen's Release for Any Alleged Past Infringement of the Ravgen Licensed Patents.** Subject to the provisions of this Agreement, and the receipt by Ravgen of [Licensee's] payment under Section 3.1, Ravgen, on behalf of itself and Ravgen Releasing Parties, hereby irrevocably, unconditionally, absolutely and forever, releases, acquits and discharges the [Licensee] Released Parties from any claim, counterclaim, demand, allegation, damage, loss, debt, liability, account, reckoning, indemnity, obligation, cost, expense, lien, attorneys' fee, any other action or cause of action of any kind and nature, whether at law or in equity, now known or unknown, suspected or unsuspected, asserted or unasserted, matured or unmatured, disclosed and undisclosed, for any alleged past infringement of the Ravgen Licensed Patents prior to the Effective Date of this Agreement, or for any acts that might be deemed infringement of the Ravgen Licensed Patents. The foregoing release shall also include the right to extend to [Licensee]'s distributors, resellers, customers, and users the right to use, offer for sale, or sell products sold by [Licensee] prior to the Effective Date.

(Dowd Decl., Ex. 3 ("PLA"), § 2.2, ECF No. 330) "[Licensee] Released Parties" are defined under the PLA as, among others:

> (d) past, current and future importers, distributors, resellers, distributors, end use and non-end use customers, purchasers and/or end users of any Covered Products, but solely to the extent of their import, purchase, possession, use or resale of Covered Products directly or indirectly from [Licensee] or its Affiliates

(*Id.* § 1.10 (emphasis added).) The PLA further defines "Covered Products" to mean "any [Licensee] or [Licensee] Affiliate product, as well as any methods, processes, services, or procedures that are employed by [Licensee] or its Affiliates in connection with manufacture, use, or sale of such product." (*Id.* § 1.2.)

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The Court concludes that under the PLA's terms, Quest is a Released Party. It is undisputed that Quest purchases certain Covered Products from Licensee and uses certain products, along with non-Licensee products, to perform QNatal. (Ravgen's GDMF Nos. C7, C8.) The parties also do not dispute that for Quest to benefit from the release between Ravgen and Licensee, Quest must qualify as a Licensee Released Party under Section 1.10. Ravgen argues the language "solely to the extent," however, limits who qualifies as a Released Party and by extension, limits the scope of the release itself. Because Ravgen alleges that Quest's QNatal test infringes the Patents-in-Suit and because Quest's use of the Licensee's Covered Products **alone** do not practice the asserted claims, Quest is not released from liability under the PLA. Put another way, Ravgen urges the Court to interpret the PLA release as follows:

> Ravgen . . . releases . . . Quest . . .solely to the extent of their . . . use . . . of [a Covered Product] . . . from any claim . . . for any alleged past infringement . . . or for any acts that might be deemed infringement of the Ravgen Licensed Patents.

(Ravgen Oppo. at 20, ECF Nos. 249, 324.)

The plain terms of the PLA do not support Ravgen's strained interpretation. The PLA defines Released Parties to include "past, current and future . . . end use and non-end use customers, purchasers and/or end users of any Covered Products, but solely to the extent of their import, purchase, possession, use or resale of Covered Products directly or indirectly from [Licensee] or its Affiliates." (PLA § 1.10.) The phrase "solely to the extent" limits the identified third-parties to the extent of their "import, purchase, possession, use or resale of Covered Products ***directly or indirectly from [Licensee] or its Affiliates***." The terms evidence an intent to limit those released to only certain third-parties who came into possession of or used Covered Products "directly or indirectly" from the Licensee or its Affiliates. This interpretation is reasonable—it precludes those who may otherwise qualify as end-users but who do not obtain Covered Products "directly or indirectly" from Licensee or its Affiliates.

In addition, other sections of the PLA contradict Ravgen's argument that the parties did not intend to release third parties who use Covered Products *in connection* with a method or system.

> **No Other Rights**. No rights, licenses, covenants, or releases are granted under any patents except as expressly provided herein, whether by implication, estoppel or otherwise. No right to grant covenants, rights, sublicenses, or to become a foundry for Third Parties is granted under this Agreement. **The Parties agree that, except as expressly set forth herein, the releases and covenants set forth in this Agreement (including Section 2) expressly exclude any methods, systems, products, services and/or components**

> **(collectively "Systems") of any Third Party** ***except in those instances where such Third Party Systems are sold and/or used as part of, or together with, a [Licensee] Covered Product***.

(PLA § 2.11 (emphasis added).) The parties expressly account for the instance where a third-party's method or system would be excluded under the PLA's releases and covenants. But in doing so, the parties made clear that those methods or systems are excluded "except in those instances where such Third-Party Systems are sold and/or used as part of, or together with, a [Licensee] Covered Product." While Ravgen asserts that its infringement claims against Quest go *beyond* the use of certain Covered Products, it is undisputed that Quest uses Covered Products to perform the QNatal test. (Ravgen GDMF No. C8.) The PLA, and its release, therefore, cover even these instances where Quest's QNatal is "used as part of, or together with," a Covered Product.

Accordingly, the Court finds that Quest qualifies as a Released Party under the PLA and is released for "any alleged past infringement of the Ravgen Licensed Patents prior to the Effective Date of this Agreement, or for any acts that might be deemed infringement of the Ravgen Licensed Patents" that occurred prior to June 23, 2021.[2]

B. Non-Infringement of Ravgen's '277 Patent

Having determined that Quest is released for liability for infringing conduct occurring before June 23, 2021, the Court now turns to the issue of Quests' non-infringement of the '277 Patent.

Under the Patent Act, 35 U.S.C. § 271, liability for patent infringement may be imposed on any person who, without permission of the patentee, "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore." The rights granted to the patentee are defined by the patent's claims. *Markman v. Westview Instruments, Inc.,* 517 U.S. 370, 373 (1996). In determining whether an allegedly infringing device falls within the scope of the claims, a two-step process is used: (1) the court must determine as a matter of law the meaning of the particular claim or claims at issue; and (2) it must consider whether the accused product infringes one or more of the properly construed claims. *Id.* at 384. The second inquiry is a question of fact, although summary judgment of infringement or non-infringement may nonetheless be appropriate when no genuine dispute of material fact exists. *Irdeto*

[2] The parties do not dispute that to the extent Quest is released, it is only for pre-June 23, 2021 infringement. (*See* Ravgen Oppo. at 17, fn. 15.)

Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1299 (Fed. Cir. 2004) (quoting *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998)).

The patentee bears the burden of proving infringement by a preponderance of the evidence. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991). This burden can be met by showing that the patent is infringed either literally or under the doctrine of equivalents. *See Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1318 (Fed. Cir. 2004). To support a finding of literal infringement, the patentee must establish that "every limitation recited in the claim appears in the accused product, i.e., the properly construed claim reads on the accused product exactly." *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1382 (Fed. Cir. 2000) (citing *Amhil Enters. Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 (Fed. Cir. 1996)).

The Court will first construe the claim terms at issue and then consider whether QNatal infringes on the construed claim.

1. Claim Construction

Claim construction is a question of law. *Serio-US Indus., Inc. v. Plastic Recovery Techs. Corp.*, 459 F.3d 1311 (Fed. Cir. 2006). The words of a claim are generally given their plain and ordinary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). There are two exceptions to this general rule. First, when the patentee clearly sets forth a definition of the disputed claim term other than its plain and ordinary meaning. *Thorner v. Sony Computer Entertainment America, LLC*, 669 F.3d 1363, 1365 (Fed. Cir. 2012). Second, when the patentee disavows the full scope of a claim term either in the specification or during prosecution of the patent. *Id.*

It is undisputed that Claim 125 of the '277 patent depends from Claim 1, which is a:

> A method for detecting the presence or absence of a fetal chromosomal abnormality, said method comprising: quantitating a ratio of the relative amount of alleles at a heterozygous locus of interest in a mixture of template DNA, wherein said mixture comprises maternal DNA and fetal DNA, and wherein said mixture of maternal DNA and fetal DNA has been obtained from a sample from a pregnant female, and further wherein said heterozygous locus of interest has been identified by determining the sequence of alleles at the locus of interest, and wherein said ratio indicates the presence or absence of a fetal chromosomal abnormality.

('277 Patent Claim 1.)

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Quest asserts that Ravgen admitted in a prior litigation that the claimed "ratio" requires comparing the "relative amount of alleles at a particular position on a chromosome" resulting in the "ratio of the amount of one allele relative to the amount of each other allele at that locus." (Quest Mot. at 3.) Thus, according to Quest, the ratio results in the following equation:

Claimed Ratio

$$\frac{\text{allele 1 at position X in patient sample}}{\text{allele 2 at position X in same patient sample}}$$

(Quest Reply at 1, ECF Nos. 281, 331.) Ravgen counters that Quest's interpretation improperly substitutes "particular position" for "locus of interest[,]" and implicitly limits the claim by including "the same patient sample." Ravgen also asserts that the issue in the prior litigation was whether ratios were quantitated at a single nucleotide polymorphism ("SNP"), but its claims cover more than SNPs, and therefore Quest is improperly importing "a single exemplary embodiment in an example" from the patent's specification.

Although not explicit from the parties' briefs, the parties appear to dispute two issues: (1) the meaning of the phrase "quantitating a ratio of the relative amount of alleles at a heterozygous locus of interest in a mixture of template DNA" and (2) whether the claim is limited to quantitating a ratio in "the same patient sample." Neither party however clearly provides proposed constructions for any disputed terms, and it is not this Court's burden to crystallize the parties' theories. *See Greenland v. Harbor Freight Tools USA, Inc.*, No. CV 14-05867-RGK (EX), 2015 WL 12672093, at *2 (C.D. Cal. Jan. 27, 2015). Nevertheless, the Court must determine the proper meaning and scope of the disputed claim before it can reach whether QNatal infringes on the '277 Patent. *See Markman*, 52 F.3d at 976. Therefore, the Court will interpret the disputed terms using their plain and ordinary meaning, unless the patent expressly defines certain terms. (*See* Ravgen Oppo. at 4 (Ravgen conceding "[o]ther than the two agreed-upon terms [allele and locus of interest], the claim terms are clear on their face and need no construction.").)

a. "[Q]uantitating a ratio of the relative amount of alleles at a heterozygous locus of interest in a mixture of template DNA"

The patent defines the terms "allele" and "locus of interest" and neither party appears to dispute as much. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (noting that where an inventor defines "the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision.") Allele is defined as "one of several alternate forms of a gene or non-

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coding regions of DNA that occupy the same position on a chromosome." (*See* Patent 29:11–13, Quest's SUF No. A9.) "Locus of interest" is defined as "a selected region of nucleic acid that is within a larger region of nucleic acid." ('277 Patent 29:6-10.) Incorporating the patent's express definitions for these two terms, the Court construes "quantitating a ratio of the relative amount of alleles at a heterozygous locus of interest in a mixture of template DNA" to mean "quantitating a ratio of the relative amount of one of several alternate forms of a gene or non-coding regions of DNA that occupy the same position on a chromosome at a heterozygous selected region of nucleic acid that is within a larger region of nucleic acid in a mixture of template DNA[.]"

b. No "same patient sample" limitation

Contrary to Quest's assertion, there is no express limitation to quantitating a ratio of alleles at a heterozygous locus of interest "in [the] same patient sample" in the patent. The claim's terms provide for a method for quantitating a ratio of the relative amount of alleles "in *a* mixture of template DNA[.]" The claim goes on to define the "mixture of template DNA" to mean "wherein said mixture *comprises* maternal DNA and fetal DNA, and wherein said mixture of maternal DNA and fetal DNA *has been obtained from a sample from a pregnant female*." ('277 Patent Claim 1 (emphasis added).) "[A]n indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'" *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008) (citation omitted). "The exceptions to this rule are extremely limited: a patentee must 'evince[ ] a clear intent' to limit 'a' or 'an' to 'one.'" *Id.* Meaning, "[a]n exception to the general rule arises *only* 'where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule.'" *01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012) (emphasis in original) (citing *Baldwin*, 512 F.3d at 1342–43). The claim here contains such open-ended language, and Quest has not presented anything to overcome the general rule that "a" means "one or more."

Accordingly, the Court construes Claim 1 to include the patentee's definitions for the terms "allele" and "locus of interest" and construes the remainder of the claim's terms by their plain and ordinary meaning, without the Quest proposed limitation: "the same patient sample." Thus, Claim 1 is construed as follows:

> A method for detecting the presence or absence of a fetal chromosomal abnormality, said method comprising: quantitating a ratio of the relative amount of one of several alternate forms of a gene or non-coding regions of DNA that occupy the same position on a chromosome at a heterozygous selected region of nucleic acid that is within a larger region of nucleic acid in a mixture of template DNA, wherein said mixture comprises maternal DNA and fetal DNA, and wherein said mixture of maternal DNA and fetal DNA has been

obtained from a sample from a pregnant female, and further wherein said heterozygous selected region of nucleic acid that is within a larger region of nucleic acid has been identified by determining the sequence of one of several alternate forms of a gene or non-coding regions of DNA that occupy the same position on a chromosome at the selected region of nucleic acid that is within a larger region of nucleic acid, and wherein said ratio indicates the presence or absence of a fetal chromosomal abnormality.

2. *Infringement*

Now that the claim has been construed, the Court turns to whether it covers the accused system (QNatal), either literally or under the doctrine of equivalents.

a. Literal Infringement

Material disputes of fact exist as to whether QNatal literally infringes on Claim 1. Quest asserts that it uses a method called "massively parallel shotgun sequencing" to sequence the whole genome "which looks at DNA fragments across the full length of the human genome in a given sample" to produce "sequence reads." (Ravgen's GDMF No. A13–15.) The sequenced DNA is aligned against a reference genome to place into "bins." (Ravgen's GDMF No. A17; *see* Feddeler Decl., Ex. BB at 94:22-95.) Thereafter, "for each bin, the QNatal algorithm counts the total number of sequences reads that have successfully aligned and been placed in that bin" and determines a "z-score." (Ravgen's GDMF Nos. A20-21.) Quest's experts opine that the "z-score" does not quantitate a ratio of *alleles*, let alone alleles at *a locus of interest*. (Quest Mot at 6; Dowd Ex. 14, ¶ 13.) Ravgen's experts counter that the QNatal's "z-score" "compares the observed relative amount of sequence reads versus the expected relative amount at the same locus in the genome" and its "bin-level z-score" is a ratio that compares the observed amount of alleles at a particular bin, or locus of interest, to the expected relative amount of alleles at the same locus." (Ravgen's GDMF No. A21; Feddeler Decl., Ex. AT ¶¶ 285-8.) Whether QNatal "quantitates a ratio of alleles at a heterozygous locus of interest," therefore is a question of fact that is best left for the jury, making summary judgment inappropriate.

b. Doctrine of Equivalents

There is a triable issue of fact as to whether the construed claim covers QNatal under the doctrine of equivalents. Quest's sole argument is that Ravgen is estopped from using the doctrine of equivalents to cover its QNatal's "z-score" method. (Quest Mot. at 7.) Specifically, Quest asserts that during prosecution the examiner rejected '277 Patent Claim 1, finding that certain prior art disclosed Ravgen's ratio method. To overcome the rejection, Ravgen "distinguished the ratio method from the prior art" by arguing the Ravgen method "involve[s] quantitating the relative amount of alleles at a locus

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of interest" while the prior art "compares amounts of DNA sequences ***at different*** chromosomal locations"—the method which Quest argues is similar to QNatal. (*Id.*) But as discussed above, there remains a material dispute as to whether QNatal "quantitates a ratio of alleles." If it does, there is a dispute over whether it does so at a heterozygous locus of interests as opposed to different chromosomal locations. (*See* Ravgen's GDMF Nos. A15–A22.) Thus, summary judgment is not appropriate on the theory of doctrine of equivalents.

Accordingly, the Court **DENIES** Quest's Motion as to non-infringement.

C. Inequitable Conduct

Quest's final argument is that the '277 Patent is unenforceable because of inequitable conduct. Ravgen also moves for summary judgment on this issue. The Court finds that there are triable issues of fact which preclude summary judgment for either party.

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). An alleged infringer must establish inequitable conduct "by clear and convincing evidence that the patent applicant (1) misrepresented or omitted information material to patentability, and (2) did so with specific intent to mislead or deceive the PTO." *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1344 (Fed. Cir. 2013) (citations omitted). The specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence." *Therasense, Inc.,* 649 F.3d at 1290. As such, "when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Id.* at 1290–91. Intent to deceive the patent office can be shown by direct or circumstantial evidence. *Id.* at 1290.

On January 30, 2007, the PTO Examiner rejected certain proposed claims and explained that "absent an unexpected result," Ravgen's claims "would have been prima facie obvious to the ordinary artisan at the time of the invention[.]" (Dowd Ex. 18, at -2879, -2928–30.) On May 30, 2007, Ravgen responded raising several responsive arguments, including that it had "discovered that the addition of a cell lysis inhibitor to a sample prior to determining the sequence of a locus of interest on free fetal DNA can significantly and unexpectedly increase the proportion of fetal DNA versus maternal DNA obtained from a sample[.]" (*See* Dowd Ex. 23, at -3027.) On September 26, 2007, the PTO reversed its rejection and deemed the '277 Patent claims allowable "in light of the applicant's amendment . . . and the persuasive argument(s)." (Dowd Decl., Ex. 26.) Quest asserts that "following similar Ravgen arguments during a later prosecution of a related patent, the Examiner" allowed the claims and stated "[t]he most persuasive argument(s) related to the applicant['s] assertion that there was a long felt need and the evidence of an unexpected result[.]" (Quest's SUF No. B30.)

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Quest argues that during this prosecution, Ravgen intentionally omitted several material publications that were material. Among the omitted references were publications that address a study published in 2004 by Dr. Dhallan in the Journal of the American Medical Association ("JAMA") which contained data and results regarding the increase of free fetal DNA after treating a pregnant woman's blood with formaldehyde. (Ravgen's GDMF No. B5.) Certain laboratories attempted to replicate the study and published articles that purportedly questioned the credibility of Dr. Dhallan's results ("JAMA Commentaries"). (Quest's SUF Nos. B7–B8.) It is undisputed that, at least as of January 2007, Dr. Dhallan and Dr. Cronin, his patent attorney, knew about these publications. (Ravgen's GDMF Nos. B14–B15.) Therefore, Quest argues that because others in the community considered Dr. Dhallan's results questionable, Ravgen did not disclose these references to the PTO with intent to deceive.

The Court finds that there are disputes of material fact as to whether Dr. Dhallan and Dr. Cronin had the requisite specific intent to deceive the PTO.

While there is no dispute that Dr. Dhallan and Dr. Cronin knew about the JAMA Commentaries and did not disclose them to the PTO, this is insufficient to find that the "single most reasonable inference" is that they intended to deceive the PTO. *Theransense, Inc.*, 649 F.3d at 1290 ("[a] finding that the misrepresentation or omission amounts to gross negligence or negligence under a "should have known" standard does not satisfy this intent requirement.")

While Quest's evidence suggests the Examiner would have benefitted from knowing that like-minded people in the field faulted Dr. Dhallan for failing to address the "controversy" between his results and the conflicting data from the JAMA Commentaries, (*see* Dowd Decl., Exs. 29, 32), Ravgen presented evidence that the doctors did not believe the JAMA Commentaries to be relevant comparisons. Dr. Cronin testified that "[t]here was no consideration on whether to disclose" the references which, according to him used different protocols and thus had "no bearing" on the patent claims. (Feddeler Decl., Ex. AJ.) Dr. Dhallan testified that after reviewing certain publications, he concluded that "they did not follow the protocols" set out in his JAMA 2004 article and therefore he believed these references were not "relevant comparisons[.]" (Feddeler Decl., Ex. AK.) There is also evidence that Dr. Dhallan and Dr. Cronin were both aware of another publication which tended to *support* the claimed methods findings but did not disclose this to the PTO either. (Quest's RSUF Nos. 65–66.) According to Ravgen, failure to disclose both positive and negative material to the PTO tends to negate that there was specific intent to deceive.

Based on the evidence presented by both parties, there are multiple inferences which could be drawn, not a "single most reasonable inference," as to why the Dr. Dhallan and Dr. Cronin did not

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disclose the known publications to the PTO. *Therasense, Inc.*, 649 F.3d 1298. Having found a dispute as to the element of specific intent, the Court need not address whether the omitted references are material.

Accordingly, the Court **DENIES** Quest's Motion on the issue of inequitable conduct. Having determined there exists material disputes of fact, the Court also **DENIES** Ravgen's Motion for Partial Summary Judgment on this issue.

V. CONCLUSION

For the foregoing reasons, the Court **GRANTS IN PART and DENIES IN PART** Quest's Motion for Summary Judgment, as follows:

- Quest's Motion as to the PLA release is **GRANTED**. Quest is not liable for alleged conduct occurring before June 23, 2021.
- Quest's Motion as to non-infringement and inequitable conduct is **DENIED**.

Ravgen's Motion is **DENIED** in its entirety.

Thus, the case will proceed to trial on all issues aside from whether Quest is released under the PLA.

IT IS SO ORDERED.

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